DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District
6751 Steger Dr.
Cincinnati, OH 45237

September 8, 2003

VIA FEDERAL EXPRESS

Robert Vail
Chairman of the Board
Vail Products, Inc.
235 First Street
Toledo, OH 43605

WARNING LETTER – CIN-03-18277

Dear Mr. Vail:

An inspection of your medical device manufacturing firm located in Toledo, OH was conducted by the Food and Drug Administration (FDA) on June 16 – 19, 2003. The inspection revealed that your enclosed electric hospital beds are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820. Most of these deviations have been brought to your attention previously following FDA inspections on March 17 - 18, 1997 and March 25 – 27, 1998.

The deviations are as follows:

1. Failure to establish a quality system that meets the requirements of 21 CFR 820. **[21 CFR 820.5]**

2. Failure to establish an effective management control system as required by **21 CFR 820.20**. For example:
   a. No management representative has been appointed.
   b. No quality policy has been implemented or documented.
   c. No quality plan has been established.
   d. Management reviews of the quality system have not been conducted.
   e. Quality system procedures have not been defined.

3. Failure to establish procedures for quality audits and to conduct such audits. **[21 CFR 820.22]**

4. Failure to establish and maintain procedures for implementing corrective and preventive action. **[21 CFR 820.100]**

5. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. **[21 CFR 820.30]**

6. Failure to maintain a device master record in accordance with 21 CFR 820.40 that includes device specifications and production process specifications. **[21 CFR 820.181]**

7. Failure to maintain device history records to demonstrate that the device is manufactured in accordance with the device master record. **[21 CFR 820.184]**

8. Failure to establish and maintain adequate procedures for receiving, reviewing and evaluating complaints by a formally designated unit. **[21 CFR 820.198]**

9. Failure to establish and maintain procedures to control product that does not conform to specified requirements. **[21 CFR 820.90]**

10. Failure to establish and maintain procedures for finished device acceptance and to document finished device acceptance activities. Failure to prevent finished devices from being distributed until after the acceptance criteria have been met. **[21 CFR 820.80(d)&(e)]**

11. Failure to establish and maintain procedures for in-process product acceptance. **[21 CFR 820.80(c)]**

12. Failure to identify the acceptance status of product throughout manufacturing, packaging, labeling, installation and servicing of product to assure that only acceptable product is distributed, used or installed. **[21 CFR 820.86]**

13. Failure to establish and maintain procedures to ensure that inspection, measuring, and testing equipment is routinely calibrated, inspected, checked and maintained. **[21 CFR 820.72(a)]**

14. Failure to establish and maintain procedures to ensure that manufacturing equipment is properly maintained. **[21 CFR 820.70(g)]**

15. Failure to establish training procedures for identifying training needs and to ensure that training is documented. **[21 CFR 820.25(b)]**

16. Failure to maintain in-process component test records for the required time period. **[21 CFR 820.180(b)]**

Furthermore, this inspection revealed that your firm's enclosed bed systems are misbranded within the meaning of Section 502(t)(2) of the Act. Our inspection revealed that your firm initiated a correction for the enclosed bed systems in April 2003 and did not submit a Report of Correction or Removal to FDA as required by **21 CFR 806.10** within ten working days. Please submit a Report of Correction or Removal to:

A. Wayne Edwards, Recall Coordinator
Food and Drug Administration
Cincinnati District Office
6751 Steger Dr.
Cincinnati, OH 45237

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each applicable requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

We have reviewed your firm's response to the inspectional observations, which we received on August 4, 2003. We are unable to evaluate the effectiveness of your response because it does not contain sufficient documentation of your corrective actions.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so that this information may be taken into account when awarding contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the deficiencies have been corrected.

To assist FDA in determining that corrections have been made, and thereby withdraw its advisory to other federal agencies concerning the award of government contracts and resume marketing clearance for Class III devices for which a 510(k) premarket notification or Premarket Approval application (PMA) has been submitted, we are requesting that you submit to this office certification by an outside expert consultant who has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS/GMP regulation (21 CFR Part 820). Please also submit a copy of the consultant's report, and certification by your firm's Chief Executive Officer that the consultant's report has been reviewed and that corrective action has been initiated or completed for all items in the report.

The initial certification of audit and corrections and subsequent certification of updated audits and corrections should be submitted to this office by the following dates:

- Initial certification by consultant and establishments – February 5, 2004
- Subsequent certifications – February 5, 2005 and February 5, 2006

Your firm's response to the inspectional observations, states the process of researching and scheduling interviews with GMP consultants has began. You may find the attached guidance helpful in selecting a qualified consultant.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, prosecution, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you will be taking to comply with our request.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 6751 Steger Dr., Cincinnati, OH 45237

Sincerely,

Deborah Gale
for Carol A. Heppe
Director, Cincinnati District

Enclosure: